April 10, 2026

1987 Media Limited
% Andrew Donn
Senior Regulatory Consultant
MD Compliance Limited
234 West George Street
Glasgow, G24QY
UNITED KINGDOM

Re: K252485
Trade/Device Name: ClenchNoMore (CNM-1 (Mixed sizing)); ClenchNoMore (CNM-L (Large size)); ClenchNoMore (CNM-S (Small size))
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 5, 2025
Received: August 7, 2025

Dear Andrew Donn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252485 ?

Please provide the device trade name(s). ?

ClenchNoMore (CNM-1)
ClenchNoMore (CNM-L)
ClenchNoMore (CNM-S)

Please provide your Indications for Use below. ?

ClenchNoMore is indicated for protection against bruxism or night-time teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

Please select the types of uses (select one or both, as applicable). ?

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252485

510(k) Summary

Prepared on: 2026-04-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	1987 Media Limited
Applicant Address	Alfa House Molesey Road Walton-On-Thames KT123PD United Kingdom
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Applicant Contact	Mr. Thomas Hartnett
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Correspondent Contact Telephone	+16047230524
Correspondent Contact	Dr. Andrew Donn
Correspondent Contact Email	andrew@mdcompliance.co.uk

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ClenchNoMore (CNM-1); ClenchNoMore (CNM-L); ClenchNoMore (CNM-S)
Common Name	Mouthguard
Classification Name	Mouthguard, Over-The-Counter
Regulation Number	Not Applicable
Product Code(s)	OBR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231865	Mouth Guard (ATG0603R)	OBR

Device Description Summary

21 CFR 807.92(a)(4)

ClenchNoMore is an over the counter (OTC) device intended to be used by lay people in the home environment for protection against the effects of night-time teeth grinding. The one-piece guard is constructed of a thermoplastic ethylene-vinyl acetate copolymer and is fitted by moulding the bite pads of the guard to the user's teeth after the guard has been heated

via submersion in boiled water. The moulding of the thermoplastic material provides a personalised fit for the user. The fully occlusive guard is worn on the teeth, maintaining separation between the upper and lower teeth, thereby reducing the noise and damage associated with teeth grinding. ClenchNoMore is intended for individuals age 18 and older.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ClenchNoMore is indicated for protection against bruxism or night-time teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications and intended use are the same as the primary predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The following information compares the ClenchNoMore devices to the chosen predicate and reference devices with respect to intended use and technological characteristics. This comparison of the devices provides detailed information demonstrating the basis for the determination of substantial equivalence. Any minor differences are discussed.

Proposed Device:

Trade Name / Device Name: ClenchNoMore Mouth Guard
510(k) Number: K252485
Date Cleared: TBD
Original applicant: 1987 Media Ltd

Predicate Device:

Trade Name / Device Name: Mouth Guard
510(k) Number: K231865
Date Cleared: 11/06/2023
Original applicant: Reazeal Corp.

Reference Device 1:

Trade Name / Device Name: DenTek Ultimate™ Dental Guard
510(k) Number: K180933
Date Cleared: 09/17/2018
Original applicant: Medtech Products

Reference Device 2:

Trade Name / Device Name: Zyppah Anti-Snoring Device
510(k) Number: K182312
Date Cleared: 12/26/2018
Original applicant: Always More Marketing, Inc.

Comparison :

Regulatory Class: Unclassified: Same as predicate device

Name of Generic Device Type: Mouthguard, Over-the-Counter: Same as predicate device

Regulation: N/A: Same as predicate device

Product Code: OBR: Same as predicate device

Applicable Performance Standards or Special Controls: None specified by FDA for Product Code OBR: Same as predicate device

Intended Use: Keep upper and lower teeth separated during sleep: Same as predicate device

OTC Use: Yes: Same as predicate device

Indications for Use: Indicated for protection against bruxism or night-time teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding: Same as predicate device

Target Population: Adults 18: Same as predicate device

Technological Characteristics Flexible, mouldable guard used as a barrier between teeth: Same as predicate device

Contact Materials: Ethylene-vinyl acetate copolymer: Same as predicate device

Other Materials: None: Same as predicate device

Design / Presentation: Full occlusion, boil-and-fit dental guard. Same as predicate device

Method of Manufacture: Injection molding: Same as predicate device

Method of Cleaning: Toothpaste and/or mouthwash after each use. Rinse with cold water: Same as reference device 1

Fit/Dimensions: Two sizes (small and large) via boil- and-fit. Large: 51.5mm x 67.4mm x 18.3mm Small: 45.5mm x 56.7mm x 15.1mm: Similar to predicate device: Though not identical the dimensions of the proposed devices are similar to that of the predicate device (dimensions of the large size of the proposed device are within 10% of the predicate device). Fitting to the user's individual dentition is achieved primarily by moulding for proposed and predicate devices. The inclusion of a small size of the proposed device allows users with smaller anatomy to achieve a more optimal fit without having to manually alter (trim) the devices (actions which are described in the instructions for use of both the proposed and predicate devices). The minor differences in sizes and the availability of two sizes will not affect the safety and effectiveness of the proposed device or its indications for use or intended use when compared to the predicate device.

Multiple Use Device: Yes: Same as predicate device

Sterility: Non-sterile: Same as predicate device

Leaflet included: Yes: Same as predicate device

Use environment: Home: Same as predicate device

Anatomical site of use: Oral Cavity: Same as predicate device

Site of use: Upper or lower teeth (upper recommended): Same as predicate device

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent when it has the same intended use and technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), ClenchNoMore has the same intended use and technological characteristics as the legally marketed predicate and reference devices (K231865, K180933 and K182312). Any differences between the subject device and the cited predicate and reference devices are minor and do not raise any questions of safety or effectiveness. This application establishes that the device is as safe and effective as the predicate and reference devices (K231865, K180933 and K182312). The ClenchNoMore is, therefore, substantially equivalent to the cited predicate and reference devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was performed to the proposed device in general accordance with ANSI/ ADA No. 99:2001 (reaffirmed in 2023), measuring the hardness (section 6.1), tear strength (section 6.2) and water adsorption (section 6.4) to demonstrate its effectiveness.

The non-clinical bench testing of the ClenchNoMore mouthguard demonstrates that the device meets the physical property requirements for hardness, tear strength, and water adsorption in accordance with ANSI/ADA Specification No. 99:2001 (R2023). These results confirm that the device exhibits appropriate mechanical integrity, material performance, and stability under simulated intraoral

conditions, supporting a determination of substantial equivalence to the predicate device.

Biocompatibility was addressed using FDA Biocompatibility Guidance: 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and ISO 7405 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry'.

The results of the testing concluded that the proposed device is considered non-toxic, non-sensitizing and is not an intracutaneous irritant. The results of the studies further support a determination of substantial equivalence to the predicate device.

Not Applicable

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.